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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,802	11/09/2001	Anne Chew	MWH-0002US2	7301

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GENAISSANCE PHARMACEUTICALS
5 SCIENCE PARK
NEW HAVEN, CT 06511

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,802	CHEW ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-20-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

NOTE: The claims have been renumbered in accordance with rule 1.126. No claim 2 or claim 23 were present in the claims as originally filed. Thus, claims 1, 3-22, 24-27 were renumbered as 1-25. The preliminary amendment filed 11/9/01 was entered in accordance with the renumbered claims. Claims 10 and 20-25 are pending and subject to restriction as set forth herein.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 10, drawn to an antibody, classified in class 530, subclass 387.1.

   II. Claim 20, drawn to a method of predicting a haplotype pairs, classified in class 702, subclass 19.

   III. Claims 21-22, drawn to methods of associating a phenotype and a haplotype, classified in class 436, subclass 501.

   IV. Claim 23, drawn to a computer system, classified in class 711, subclass 100.

   V. Claim 24, drawn to a genome anthology, classified in class 707, subclass 1.

   VI. Claim 25, drawn to a method of haplotyping, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I is unrelated to the methods of inventions II, III, and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed for use together. The

antibodies of invention I are not disclosed as being useful for or in the methods of inventions II, III, and VI.

3. Inventions in Group I, IV, and V are distinct because the Inventions in these groups have different modes of operation, different functions, or different effects. The antibodies, computer system, and genome anthologies are drawn to multiple, distinct products. The antibodies are composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The antibodies function in immunoassays. Further the computer systems are composed of, e.g., a CPU, a display device, an input device, etc., and function in, e.g., methods of electronic sequence comparison. The genome anthology is a collection of nucleic acid isogenes and may be used for nucleic acid analysis. Accordingly, the products of each of these Groups differ structurally and functionally from each other. As products of different sets of Groups differ from each other in structure, function, and effect, they do not belong to a recognized class of chemical compound, or have both a "common property or activity" and a common structure and are therefore properly distinct inventions.

4. Inventions in Group II, Group III, and Group VI, are distinct because the Inventions in these groups have different modes of operation, different functions, or different effects. In particular, the haplotyping method of Group VI has different functions and effects from the other methods since it operates by determining sets of polymorphisms in their relationship to one another on single chromosomal strands and results in the identification of haplotypes or strings of single nucleotide polymorphisms which may be present in particular populations. The haplotyping methods of require steps of identifying haplotypes and haplotype pairs to achieve the objectives of haplotyping.

The method of predicting haplotype pairs of Group II differs from Group VI in that it functions to identify actual information present in populations regarding two different haplotypes, rather than simply. The predictive methods require steps of identifying two polymorphisms in a gene to achieve the objective of "predicting a haplotype pair". The method of associating a phenotype with a haplotype is distinct from the previous groups because it requires determination of information about populations and the correlation of that information with haplotypes. Thus, the association methods requires steps of comparing frequencies of haplotypes in a population to achieve the objective of "identifying an association between a trait" and a haplotye. Each of these groups has results and steps different from each other group.

5. Invention II, III, and VI are unrelated to inventions IV and V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of inventions II, III and VI are not disclosed as using the products of groups IV and V.

Further Restriction Requirement

6. This application contains claims directed to the following patentably distinct subgroups of the claimed inventions. These subgroups are independent and distinct because each polymorphic site and each molecule containing said polymorphic site is structurally and functionally distinct from each other polymorphic site and molecules containing said site. The chemical structure of each polymorphism and of each molecule containing the same differ from each other. For example, a polynucleotide comprising PS1 is chemically, structurally, and functionally different from a molecule comprising PS3. Further, with particular respect to the haplotype and genotyping

claims, it is noted that the haplotypes and genotypes encompassed by these claims are also distinct from each other and from the single polymorphisms recited. For example, a molecule of haplotype 1, comprising a particular combination of polymorphisms, differs chemically, structurally, and functionally from a molecule of haplotype 2 and from a molecule comprising a single polymorphism (e.g., PS1).

7. In order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

8. Within group I, there are 53 independent and distinct inventions, wherein each invention is drawn to an isolated antibody specific for and immunoreacitve with an isolated polypeptide comprising an amino acid sequence which is a polymorphic variant for the IL4Rα protein wherein the polymorphic variant is encoded by an isogene defined by one of the fifty three haplotypes shown in table 5. To be clear, if applicant elects group I, applicant should also elect a single haplotype from table 5 that encodes the polymorphic variant for which the antibody is specific and immunoreactive.

7. Within group III, there are 53 independent and distinct inventions, wherein each invention is drawn to a method for identifying an association between a trait and one of the 53 haplotypes recited in table 5. To be clear, if applicant elects group III, applicant should also elect a single haplotype from table 5 for examination in the method of group III.

8. Within group V, there are a multitude of independent and distinct inventions, wherein each invention a genome anthology comprising a combination of isogenes defined by haplotypes 1-53 shown in table 5. The claim, as written, is unclear if the claimed anthology is required to have all

of the isogenes defined by the haplotypes 1-53, or if the anthology is to have only a subset of the isogenes. Thus, this restriction is applied to the broader interpretation wherein the anthology comprises isogenes defined by haplotypes 1-53 but does not require all 53 isogenes to be present. To this end, if applicant elects group V, applicant should elect a single combination of isogenes from those recited in table 5 for requirement in the genome anthology.

9. Within group VI, there are 53 independent and distinct inventions, wherein each invention is drawn to a method for determining whether an individual has one of 53 haplotypes recited in table 5. To be clear, if applicant elects group VI, applicant should also elect a single haplotype from table 5 for examination in the method of group VI.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches for each Group would be divergent from each other Group, so restriction for examination purposes as indicated is proper.

11. With regard to the different Inventions, the burden of search exists because a different search is required for each separate PS site, haplotype and molecule. For example, in order to properly search PS1, this haplotype will need to be searched in the Registry file of STN, in the computer database maintained by the STIC and will also require individualized searching in papers which disclose polymorphisms in the AGTR1 gene. Each paper, and as of the filing date of containing disclosure pertinent to the gene disclosure or the polypeptide that may discuss polymorphisms in the gene will need to be separately reviewed. Potentially, any of these papers could be relevant to the claimed invention. Review of this information would be different for each PS site, haplotype and molecule and would be burdensome.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Juliet C. Einsmann
Examiner
Art Unit 1634

February 21, 2003